



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL - 2 1999

6544 '99 JUL -6 P1:41

The Honorable Barney Frank
House of Representatives
Washington, D.C. 20515-2104

Dear Mr. Frank:

Thank you for your letter of June 15, 1999 concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients . . ." FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation (21 CFR 179), are enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR has been extended to July 19, 1999.

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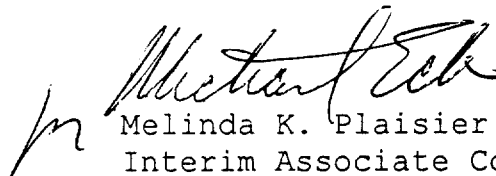
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We have forwarded your correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of irradiated foods will take into account all of the data and information received.

Because you may be concerned about irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this responds to your concerns.

Sincerely,

A handwritten signature in cursive script, appearing to read "Melinda K. Plaisier".

Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

Enclosures

cc: Dockets Management Branch
(98N-1038)

BARNEY FRANK
4TH DISTRICT, MASSACHUSETTS

2210 RAYBURN BUILDING
WASHINGTON, DC 20515-2104
(202) 225-5931

29 CRAFTS STREET
SUITE 375
NEWTON, MA 02458
(617) 332-3920

Congress of the United States
House of Representatives
Washington, DC

June 15, 1999

558 PLEASANT STREET
ROOM 309
NEW BEDFORD, MA 02740
(508) 999-6462

222 MELKEN PLACE
THIRD FLOOR
FALL RIVER, MA 02721
(508) 674-3551

89 MAIN STREET
BRIDGEWATER, MA 02324
(508) 697-9403

Dr. Jane Henney
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner,

I was only recently made aware of the pending decision about labels involving irradiation of food. I am a very strong believer in giving consumers maximum information. Those who have some objection to irradiation should be given the information that they need to make their decisions. The opinion of others on the scientific validity of their arguments should not be a barrier to their being informed so that they can act according to their own wishes. Thus I urge you to retain some requirement that there be explicit reference to "irradiation" in food which has been so treated.


BARNEY FRANK

No. 99-4146